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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,384	06/01/2001	Derek J. Hei	282172000810	5308

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EXAMINER	
MILLER, MARINA I	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 05/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/872,384	HEI, DEREK J.	
	Examiner	Art Unit	
	Marina Miller	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-25* is/are pending in the application.

4a) Of the above claim(s) *19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *01 June 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *10/4/04;5/28/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

9.0.0.

DETAILED ACTION

Applicant's submission filed on 10/4/2004 is acknowledged. Claims 1-25 are pending. Claim 19 is withdrawn. Claim 25 is newly added. Claims 1-18 and 20-25 presently are under examination.

Information Disclosure Statement

Examiner appreciates applicant's apprising her of copending sister application 09/972,323, 10/011,202, 10/016,323, and 10/051,976. IDS filed 5/28/2004 has been considered in full. IDS filed 10/04/2004 has been considered in part. References crossed out on IDS filed 10/04/2004 have not been considered because a copy of an office action from a copending application which has not yet matured into an issued patent or otherwise become publicly available is not a proper document to be listed on PTO 1449 under 37 CFR 1.98(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-18 and 23-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant amended claim 8 to recite free psoralen having been exposed to light having a wavelength and "in an amount sufficient" to cause a pathogen to be inactivated. It is not clear if applicant intends an amount of psoralen or light to be "sufficient" to cause inactivation of psoralen. If it is the latter, then it is not clear what applicant intends an "amount" of light to be,

e.g., radian, joules, intensity over a defined area, intensity over specific time, etc. Claims 9-18 and 23-24 depend on claim 8. Thus, claims 8-18 and 23-24, as amended, are indefinite.

The rejections under 35 U.S.C. 112 ¶ 1 and 2 made in the previous Non-Final Office Action mailed 5/19/2004 are hereby withdrawn in view of the claim amendments.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6, 8-11, 13-14, 16-18, 20-23, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley, U.S. Patent 6,319,662, in view of Davankov, U.S. Patent 3,729,457.

Foley discloses a method and an apparatus for removing viral contaminants from a body fluids comprising steps of adding psoralen to a blood product, irradiating the psoralen and the blood product under conditions effective for psoralen to inactivate a pathogen, and contacting the mixture comprising free psoralen and low molecular weight psoralen photoproducts with resin and specifically, with resin capable of absorbing free psoralen and the products (see for the method steps col. 2, line 57-65). Foley discloses various resin materials, e.g., charcoal, an ion exchange resin, and biobeads (macroporous polymeric beads with a high surface area with different polarity, col. 5, line 10-18). Foley does not teach that his resins are "pre-wetted." Foley discloses 4'-primary amino-substituted psoralen (Example 1, col. 5). Foley discloses blood

products comprising plasma and platelets (col. 2, line 66, and col. 4, line 32-38). Foley discloses light irradiation having a sufficient wavelength to inactivate pathogenic agents and specifically, irradiation with red light and exposure 8 J/c m^2 (amount of light) (col. 3, line 8-11). Foley discloses resin having a surface area 150-1600 m^2/g, a pore diameter 45-300 Å , and a mesh size 20-50 (col. 5, line 18-21 and 65-66). Foley discloses a biological fluid formed by his method (col. 3, line 5-15).

Foley does not teach hypercrosslinked resin and specifically, polyaromatic resin.

Davankov discloses hypercrosslinked resin for ion-exchange chromatography (col. 1, line 49-55). Davankov does not teach "pre-wetting" his resin, and in fact, teaches that his resins may be rigid microporous structures (col. 3, line 60-63), *i.e.*, resins which do not swell or need "pre-wetting" prior to use.

It would have been obvious to one skilled in the art at the time of the invention to modify the method of Foley to use hypercrosslinked resin for an ion-exchange chromatography, such as taught by Davankov, where the motivation would have been to improve penetration of ions through the whole volume of an ionite granulate, to provide a mechanically strong macronet polystyrene structure with chemically stable bridges, and to improve exchange capacity, osmotic stability, and kinetic characteristics, as taught by Davankov, col. 2-3.

Claims 7 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley, U.S. Patent 6,319,662, in view of Davankov, U.S. Patent 3,729,457, as applied to claims 1-6, 8-11, 13-14, 16-18, 20-23, and 25 above, and in view of Wollowitz, U.S. Patent 5,593,823.

Foley and Davankov make the method of claims 1-6, 8-11, 13-14, 16-18, 20-23, and 25 obvious, as set forth above.

Foley and Davankov do not discloses 4'-(4'-amino-2-oxa)butyl-4,5',8-trimethylpsoralen and brominated psoralen.

Wollowitz discloses a method for inactivating pathogens in blood using photoactivated 4'-(4'-amino-2-oxa)butyl-4,5',8-trimethylpsoralen compound, col. 4, line 64-65. Wollowitz also discloses brominated psoralen (col. 14, line 24-25 and 66-67).

It would have been obvious to one skilled in the art at the time of the invention to modify the method of Foley and Davankov to use different forms of psoralen, such as taught by Wollowitz, where the motivation would have been to improve ability to inactivate pathogens without causing significant damage to blood products and without the need of removing oxygen, thereby ensuring safety, as taught by Wollowitz, col. 3, line 29-34.

Claims 12 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Foley, U.S. Patent 6,319,662, in view of Davankov, U.S. Patent 3,729,457, as applied to claims 1-3, 5-6, 8-11, 14, 16-18, 20-23, and 25 above, and in view of Hearst, U.S. Patent 4,196,281.

Foley and Davankov make the method of claims 1-3, 5-6, 8-11, 14, 16-18, 20-23, and 25 obvious, as set forth above. Foley also teaches administering treated blood products to a patient (col. 3, line 14-15).

Foley and Davankov do not disclose a synthetic medium containing phosphate.

Hearst teaches a method of using psoralen for inactivation pathogenic agents (*e.g.*, RNA virus), (*see*, for example, col. 11, line 21-25). Hearst teaches irradiating a mixture of phosphate buffer saline containing virus plaque and psoralen (col. 11, line 20-25).

It would have been obvious to one skilled in the art at the time of the invention to modify the method of Foley and Davankov to use phosphate medium, such as taught by Hearst, where the motivation would have been to use treated products for vaccine, thereby ensuring safety, as taught by Hearst (col. 11, line 20-25).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claims are not patentably distinct from the reference claims because the examined claims are either anticipated by, or would have been obvious over the reference claims. *See, e.g., In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Grouped claims (8 and 16), 10, 11, (12 and 17), (13 and 17), (14 and 18), and 15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting

as being unpatentable over claims 12, 13-16, and 19-20, respectively, of copending Application 10/051,976 ("App. '976").

Instant claim 8 is directed to a method for removing free psoralen from a biological fluid wherein psoralen was exposed to light comprising contacting the biological fluid with a hypercrosslinked resin capable of removing free psoralen and removing free psoralen from the biological fluid. Claims 10-18 further limit claim 8.

Claim 12 of App. '976 depends from claim 10. Claim 10 of App. '976 are directed to a method for removing free psoralen from a blood product after psoralen was exposed to light comprising contacting blood product with a resin of porous structure capable of removing free psoralen and removing free psoralen from the blood product. Claim 12 of App. '976 further limits claim 10 to a hypercrosslinked polyaromatic resin similar to that recited in instant claims 8 and 16. Claims 13-16, 19, and 20 of App. '976 recite the same limitation as instant claims 10, 11, (12 and 17), (13 and 17), (14 and 18), and 15, respectively.

Therefore, narrower claims of App. '976 anticipate broader claims of the instant application.

Claims 9, 19-20, and 23-24 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 11, 23-24, and 27-28, respectively, of copending Application 10/051,976 ("App. '976"), in view of claim 12 of App. '976.

The instant claims are directed to a method for removing psoralen from a biological fluid comprising blood and blood products and a biological fluid formed by the method.

The claims of App. '976 are directed to a method for removing psoralen from a blood product and a blood product formed by the method similar to that of the instant invention.

Claims 11, 23-24, and 27-28 of App. '976 do not recite hypercrosslinked resin.

Claim 12 of App. '976 recites hypercrosslinked resin.

It would have been obvious to one skilled in the art at the time of the invention to modify the method of claims 11, 23-24, and 27-28 of Appl. '976 to use hypercrosslinked resin, such as recited in claim 12 of App. '976, where the motivation would have been to improve property of resin.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marina Miller whose telephone number is (571)272-6101. The examiner can normally be reached on 8-5, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph. D. can be reached on (571)272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marina Miller
Examiner
Art Unit 1631

MM

MARJORIE A. MORAN
PRIMARY EXAMINER
5/12/05